26 February 2026
EMA/CHMP/37389/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dazparda

insulin aspart

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dazparda, intended for the treatment of diabetes mellitus.

The applicant for this medicinal product is Gan & Lee Pharmaceuticals Europe GmbH.

Dazparda will be available as a 100 unit/ml solution for injection in a pre-filled pen. The active substance of Dazparda is insulin aspart, a fast-acting insulin analogue (ATC code: A10AB05), which has a more rapid onset of action than human soluble insulin. The blood glucose lowering effect of insulin aspart is due to the facilitated uptake of glucose following binding of insulin to receptors on muscle and fat cells and to the simultaneous inhibition of glucose output from the liver.

Dazparda is a biosimilar medicinal product. It is highly similar to the reference product NovoRapid (insulin aspart), which was authorised in the EU on 7 September 1999. Data show that Dazparda has comparable quality, safety and efficacy to NovoRapid. More information on biosimilar medicines can be found here.

The full indication is:

> Dazparda is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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